REMARKS

Applicants have amended their claims in order to further clarify the definition of various aspects of the present invention. Specifically, Applicants have amended each of claims 1 and 3 to recite additional processing, subsequent to the adding, of comparing between amounts of the produced interferon-γ (IFNγ) measured in the subject animal and that in a non-infected control animal; and distinguishing the subject animal from a non-infected control animal in a case where a statistically significant increase in amounts of produced interferon-γ (IFNγ) is measured in the subject animal. Applicants have further amended claim 3 to recite inducing the cell-mediated immunological reaction against the mycobacterium which caused the disease or infection to be diagnosed by the method, providing a connection between recitations of mycobacterium and antecedent basis for the latter recitation. Note, for example, the first full paragraph on page 10; first full paragraph on page 14; the first paragraph on page 18; the first full paragraph on page 27; the paragraph bridging pages 27 and 28; and the paragraph bridging pages 28 and 29, of Applicants' specification.

In additional, Applicants are adding new claims 7-10 to the application. Claim 7, dependent on claim 3, recites that the disease or infection is tuberculosis, with the cell-mediated immunological reaction being induced by adding a tuberculosis antigen to the collected blood, the diagnostic method being a diagnostic method for tuberculosis; and claim 8, dependent on claim 7, further defines this tuberculosis antigen. Claim 9, dependent on claim 3, recites that the disease or infection is leprosy, the cell-mediated immunological reaction being induced by adding a leprosy antigen to the collected blood, the diagnostic method being a

diagnostic method for leprosy; and claim 10, dependent on claim 9, further defines the leprosy antigen. See the paragraph bridging pages 22 and 23 of Applicants' specification.

It is respectfully submitted that the entry of the present amendments is proper, notwithstanding the Finality of the Office Action mailed October 9, 2008, in light of the concurrent filing of the RCE Transmittal. In addition, it is respectfully submitted that the present amendments constitute the necessary Submission supporting the concurrently filed RCE Transmittal.

The rejection of claims 1-3 under the second paragraph of 35 USC 112, set forth in Item 5 on page 2 of the Office Action mailed October 9, 2009, is respectfully traversed, especially insofar as applicable to the claims as presently amended. Thus, claim 1 has been amended to recite comparing and distinguishing processing, after measuring an amount of produced interferon-γ in the blood. It is respectfully submitted that such comparing and distinguishing processing clearly complete the method, providing a diagnostic method as recited in claims 1 and 3. In this regard, note the contention by the Examiner in the last three lines on page 2 of the Office Action mailed October 9, 2008, that the missing essential step is a comparison of detected amounts of produced IFNγ from normal animals with that detected in animals suspected of infection. It is respectfully submitted that claims 1 and 3 now recite such comparison.

Applicants respectfully traverse the rejection of claim 3 under the first paragraph of 35 USC 112, set forth in Item 6 on page 3 of the Office Action mailed October 9, 2008, especially insofar as this rejection is applicable to the claims as presently amended. Thus, claim 3 has been amended to recite that the method is a

diagnostic method for mycobacterial disease or mycobacterial infection "caused by a mycobacterium", with the "adding" processing reciting that the specified antibody is added to the collected blood while inducing cell-mediated immunological reaction against "said" mycobacterium in the collected blood. Thus, in claim 3 as presently amended, the relationship is set forth between the disease or infection and the mycobacterium recited in the "adding" processing; i.e., the species responsible for the disease or infection.

As described throughout the present specification, cell-mediated immunological reaction against a target mycobacterium is required to be induced by using antigen from the target mycobacterium. Especially in "Comparative Example 1" of the present specification, production of IFNγ depending on the anti-IL-10 antibody concentration was not induced by non-specific stimulation with concanavalin A. It is respectfully submitted that claim 3 as presently amended in consistent with the specification, in reciting cell-mediated immunological reaction against "said" mycobacterium, this "mycobacterium" being that causing the mycobacterial disease or mycobacterial infection.

The rejection of claims 4-6 under the second paragraph of 35 USC 112, as being incomplete, set forth in Item 8 on pages 3 and 4 of the Office Action mailed October 9, 2008, is noted. As can be appreciated, claims 1 and 3, the parent claims of claims 4-6, recite processing of comparing between amounts of produced interferon-γ measured in the subject animal and that in a non-infected control animal, with the subject animal being distinguished from a non-infected control animal in a case where a statistically significant increase in amounts of produced interferon-γ is measured in the subject animal. Clearly, these additional processing recited in

claims 1 and 3, the parent claims of claims 4 and 6 and thus incorporated therein, overcome the rejection of claims 4-6 under the second paragraph of 35 USC 112, as set forth in Item 8 on pages 3 and 4 of the Office Action mailed October 9, 2008.

Reference by the Examiner in the first paragraph on page 4 of the Office Action mailed October 9, 2008, to determination of a cutoff value which determines a positive infection, is noted. However, it is respectfully submitted that a specific cutoff value need not be set forth in the present claims. It is respectfully submitted that the important factor is a comparison of IFNγ in the subject animal with that in a control animal. Note that the present invention is premised on the basis that IFNγ is not significantly produced in blood of a healthy animal. It is respectfully submitted that the amount of produced IFNγ in many healthy animals may be measured in advance, to determine a range of amount of produced IFNγ as a normal value; and then, at the time of actual diagnosis, the amount of produced IFNγ may be measured only with respect to the subject animal, comparing the result with the normal value in order to determine whether there is a statistically significant increase in the subject animal.

Applicants respectfully traverse the rejection of claim 6 under the first paragraph of 35 USC 112, as set forth in Item 9 on pages 4-6 of the Office Action mailed October 9, 2008. For the same reasons as set forth previously as to why presently amended claim 3 satisfies requirements of the first paragraph of 35 USC 112, responsive to the rejection thereof in Item 6 on page 3 of this Office Action mailed October 9, 2008 (that is, the specific relationship (identity) between the mycobacterium causing the mycobacterial disease or mycobacterial infection, and the mycobacterium recited in the "adding" processing, it is respectfully submitted that

the present claims sufficiently relate the species of disease/infection and antigen utilized, for satisfying the enablement requirement of the first paragraph of 35 USC 112. In view of this relating the species causing the disease/infection and the species in the "adding" processing, and noting the examples in Applicants' specification, of other diseases and mycobacterium, it is respectfully submitted that there is sufficient guidance to one of ordinary skill in the art to practice the present invention.

In view of the foregoing comments and amendments, and, additionally, in view of the concurrently filed RCE Transmittal, entry of the present amendments, and reconsideration and allowance of all claims presently pending in the above-identified application, are respectfully requested.

To the extent necessary, Applicants hereby petition for an extension of time under 37 CFR 1.136. Kindly charge any shortage of fees due in connection with the filing of this paper, including any extension of time fees, to the Deposit Account of Antonelli, Terry, Stout & Kraus, LLP, Account No. 01-2135 (case 1333.46042X00), and please credit any overpayments to such Deposit Account.

Respectfully submitted,

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